

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Application of:** Martin C. Hinz  
**Application No.:** 10/715912  
**Filed:** November 18, 2003  
**For:** Comprehensive Pharmacologic Therapy for Treatment of Obesity  
**Group Art Unit:** 1616

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Docket No.:** H76.2N-11128-US01

**TRANSMITTAL LETTER**

1. In regard to the above-identified application, in addition to this 2 page transmittal letter, we are submitting the attached: **4 Page Information Disclosure Statement; 2 Page List of References; 15 References and Return Postcard.**
2. With respect to fees:
  - ☒ No additional fee is required.
  - ☐ Attached is check(s) in the amount of \$
  - ☒ Charge additional fee to our Deposit Account No. 22-0350.
3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**


This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefore.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

Sincerely,

VIDAS, ARRETT & STEINKRAUS

Date: April 8<sup>th</sup>, 2004

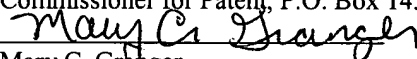
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**Certificate Under 37 CFR 1.8:** I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as FIRST CLASS MAIL, addressed to Commissioner for Patent, P.O. Box 1450, Alexandria, VA 22313-1450, on April 8, 2004.

  
Mary C. Granger



PATENT

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INFORMATION DISCLOSURE STATEMENT

Listed below or on an attached form listing the cited references and/or a copy of a PTO-892 form is information known to applicant(s). A copy of each listed publication, U.S. patent, foreign patent and U.S. patent application is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98, *except that* U.S. applications from which priority is claimed under 35 U.S.C. §120, and documents cited in such priority applications, may be omitted from the enclosures pursuant to 37 C.F.R. 1.98(d). Applicant's submission of copies of U.S. applications does not constitute a waiver of the confidentiality of such applications. As such, **Applicant requests that any copies of unpublished US applications submitted herewith be excluded from the file wrapper pursuant to 37 C.F.R. §1.14.**

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If the form listing the cited references or PTO-892 from a prior application is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is prior art, or is or is considered to be, material to patentability as defined in §1.56.

Applications that are listed on the accompanying form listing the cited references as related by priority are related by priority claim under 35 USC §120. Pursuant to 37 CFR §1.98(d), no copies of cited art in a previous application(s) to which priority was claimed need be submitted. Applicant is providing copies of the form listing the cited references and/or 892 forms from these cases.

  X   I. This statement qualifies as a no-fee Information Disclosure Statement under 37 C.F.R. §1.97(b) or otherwise because to the knowledge of the undersigned attorney it is being filed (check all that apply):

- (1) within 3 months of the filing date of the application (other than a CPA); or
- (2) within 3 months of entry of the national stage; or
- X   (3) before the mailing of a first Office Action on the merits;
- (4) before the mailing of a first Office Action after the filing of a request for continued examination (RCE) under §1.114;
- (5) as part of a continued prosecution application (CPA); or
- (6) during the period of a suspension of action for a CPA under 37 C.F.R. §1.103(b).

       II. This statement is believed to require a fee or the submission of a certification under 37 C.F.R. §1.97 (c) or otherwise. If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application (other than CPA); (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; (3) the mailing of a first Office Action on the merits; (4) the mailing of a first Office Action after the filing of a request for continued examination under §1.114; or (5) after the filing of a request for a continued prosecution application, but before the mailing date of the earlier of a final office action under §1.113, a notice of allowance under §1.311 or an action that otherwise closes prosecution in the application, then:

- (1) a certification as specified in §1.97(e) is provided below; or
- (2) a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

\_\_\_\_\_ **III. 37 C.F.R. §1.97(d).** If this statement is being filed after the mailing date of the earlier of a final office action under §1.113, a notice of allowance under §1.311, or an action that otherwise closes prosecution in the application, but before payment of the issue fee, then:

- \_\_\_\_\_ (1) a certification as specified in §1.97(e) is completed below; and  
\_\_\_\_\_ (2) a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with payment of other papers filed together with this statement.

**X** **IV. Fee Authorization.** If any fee is due for consideration of this Information Disclosure Statement and full payment has not been submitted herewith, regardless of which boxes have been checked above, the Commissioner is hereby authorized to charge any additional fees associated with this communication to Deposit Account No. 22-0350. The Commissioner is hereby authorized to credit any overpayment associated with this communication to Deposit Account No. 22-0350.

***If paragraph II.1 or III is checked, also check one of the paragraphs below***

\_\_\_\_\_ I hereby certify, under 37 CFR §1.97(e)(1), that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the date of the filing of this information disclosure statement.

\_\_\_\_\_ This communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

\_\_\_\_\_ I hereby certify, under 37 CFR §1.97(e)(2), that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.


*For the purpose of this certification, Applicant considers the PCT International Search Authority to constitute a foreign patent office.*

If this Information Disclosure Statement has been submitted without the appropriate box checked, Applicant requests that this Information Disclosure Statement be considered nevertheless if it is timely submitted under any of the provisions of 37 C.F.R. §1.97 or otherwise. Finally, if any petition is necessary to ensure consideration of this Information Disclosure Statement, Applicant requests that this be treated as such a petition.

Sincerely,

VIDAS, ARRETT & STEINKRAUS

Date: April 8, 2004

By:   
Edwin E. Voigt II  
Registration No.: 36042

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UNPUBLISHED US APPLICATIONS NOT RELATED BY PRIORITY (COPIES ENCLOSED)	ATTY DOCKET NO.: J02.4-1128-US01	APPLICATION NO. 10/715912
	APPLICANT: Martin C. Hinz	
	FILING DATE: November 18, 2003	GROUP: 1616

**OTHER ART (Including Author, Title, Date, Pertinent Pages, Ect.)**

CA	Fava, M.; Judge, R.; Hoog, S. L.; Nilsson, M. E.; Koke, S. C.; Massachusetts General Hospital, Boston 02114, USA; <i>Fluoxetine versus sertraline and paroxetine in major depressive disorder: changes in weight with long-term treatment</i> ; J. Clin Psychiatry 2000 Nov; 61(11):863-7. [MEDLINE record in process]
CB	American College of Neuropsychopharmacology Annual Meeting in San Juan; SAN JUAN, Puerto Rico, Dec. 15, 2000; PR Newswire.
CC	Leinonen, E.; Skarstein, J.; Behnke, K.; Agren, H.; Helsdingen, J.T.; Department of Psychogeriatrics, Tampere University Hospital Pitkanemi, Finland; <i>Efficacy and tolerability of mirtazapine versus citalopram: a double-blind, randomized study in patients with major depressive disorder. Nordic Antidepressant Study Group.</i> ; Int Clin Psychopharmacol, 1999 Nov; 14(6):329-37.
CD	Michael Anchors, M.D., PH.D., Professor of Medicine, Georgetown University Medical School; Anchors (US Patent 5,795,895) book; " <i>Safer than Phen-fen</i> "; page 82.
CE	Rochat, B.; Baumann, P.; Audus, K.L.; Department of Pharmaceutical Chemistry, University of Kansas, 2095 Constant Avenue, Lawrence, KS 66047, USA; <i>Transport mechanisms for the antidepressant citalopram in brain microvessel endothelium</i> ; Brain Res, 1999 Jun 12; 831(1-2):229-36.
CF	Foglia, J. P.; Pollock, B.G.; Kirshner, M.A.; Rosen, J.; Sweet, R.; Mulsant, B.; Department of Psychiatry, University of Pittsburgh, School of Medicine, PA 15212, USA; <i>Plasma levels of citalopram enantiomers and metabolites in elderly patients</i> ; Psychopharmacol Bull, 1997; 33(1):109-12.

**UNPUBLISHED US APPLICATIONS NOT RELATED BY PRIORITY**

EXAM'S INIT.	APPLICATION NO.	FILING DATE	INVENTOR(S)
DA			
DB			

US APPLICATIONS RELATED BY PRIORITY (COPIES NOT ENCLOSED)	ATTY DOCKET NO.: J02.4-1128-US01	APPLICATION NO. 10/715912
	APPLICANT: Martin C. Hinz	
	FILING DATE: November 18, 2003	FILING DATE: November 18, 2003

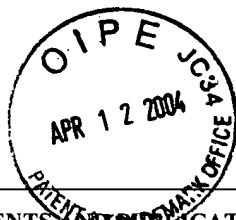
**US APPLICATIONS RELATED BY PRIORITY**

EXAM'S INIT		APPLICATION NO.	FILING DATE	PATENT NO.	INVENTOR(S)	FORM 1449/892 ENC
X	EA	09/412,701	10/05/1999	6403657	Hinz	
X	EB	09/942188	8/29/2001		Hinz	
	EC					
	ED					

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if application considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

X Did not receive



<b>LIST OF PATENTS AND APPLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)				ATTY DOCKET NO.: H76.2N-11128-US01		APPLICATION NO.: 10/715912	
				APPLICANT: Martin C. Hinz			
				FILING DATE: November 18, 2003		GROUP: 1616	
<b>REFERENCE DESIGNATION</b>				<b>U.S. PATENT AND PUBLISHED APPLICATION DOCUMENTS</b>			
EXAM'S INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	3097947	7/16/63	Kemmerer	424/617		
	AB	5480657	1/02/96	Allen	424/617		
	AC	5795895	8/18/98	Anchors	514/253		
	AD	6207699	3/27/01		514/419		
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY			
X	BA	410067663-A	3/ 1998	Japan			
	BB						
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Ect.)</b>							
	CA	Budavari et al.; <i>The Merck Index</i> ; Merck & Co., Inc.; 1989, 11 <sup>th</sup> Edition, page 2321, and 4116.					
	CB	Donald Heath; <i>Pulmonary Vascular Disease</i> ; <u>Medical Clinics of North America</u> , Volume 61/Number 6, November 6, 1997, Symposium on Pulmonary disease, pp 1279-1307.					
	CC	Jules Hirsch; <i>The Treatment of Obesity with Drugs</i> ; <u>The American journal of Clinical Nutrition</u> , January 1998, pp. 2-4.					
	CD	Griffen, MD, et al.; <i>Asymptomatic Mitral and Aortic Valve Disease Is Seen In Half of the Patients Taking 'Phen-Fen'</i> ; <u>ARCH INTERN MED</u> , Vol. 158, Jan. 12, 1998, pp. 102.					
	CE	<i>Fluoxetine (Prozac) and Other Drugs For Treatment of Obesity</i> ; published in <u>The Medical Letter on Drugs and Therapeutics</u> ; Vol. 36 (Issue 936), November 25, 1994, pp. 107-108.					
	CF	Len Griffen, MD, et al.; <i>The "Phen-Pro" Diet Drug Combination Is Not Associated With Valvular Heart Disease</i> ; <u>ARCH INTERN MED</u> , Vol. 158, June 8, 1998, pp. 1278-1279.					
	CA	Riley et al.; <u>Drugs Facts and Comparisons</u> . 1999. Pages 239 (a), 264 (d), 264 (td).					
	CB	Harvey, B.H.; Bouwer, C.D.; Department of Pharmacology, Potchefstroom University for Christian Higher Education, South Africa; <i>Neuropharmacology of paradoxical weight gain with selective serotonin reuptake inhibitors</i> ; Clin Neuropharmacol 2000 Mar-Apr; 23(2):90-7.					
	CB	Fava, M., Depression Clinical and Research Program, Massachusetts General Hospital, Boston 02114, USA, <i>Weight gain and antidepressants</i> , J. Clin Psychiatry 2000;61 Suppl 11(1-2):37-41.					
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							
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